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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,068	09/20/2001	Hazire Oya Alpar	41577/263898	6302

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/937,068	**Applicant(s)** ALPAR ET AL.	
	Examiner Ja-Na Hines	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 March 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *12 and 33*.
   Claim(s) rejected: *1, 4, 6-10, 12, 13, 29 and 33*.
   Claim(s) withdrawn from consideration: *26-28 and 30-32*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

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The proposed amendment after final will not be entered because it raises new issues that would require further search and consideration, and are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal. The proposed amendment changes the scope of the claims from a vaccine which required that the composition provide protective immunity to an undisclosed biologically active agent to now recite claims drawn to an immunostimulant which refers to an adjuvant which stimulates the immune system to increase the protective effect produced by a protective antigen. The specification teaches that the immunostimulant may be a sole compound and not a pharmaceutical composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes, the particles comprising a biologically active agent that generates a protective immune response in an animal to which it is administered', in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being selected from the group consisting of: A) polyornithine, B) a member selected from the group consisting of water soluble vitamins and water soluble vitamin derivatives, C) a member selected from the group consisting of positively charged cationic block copolymers and positively charged cationic surfactant:, D) a clathrate, E) a complexing agent, F) cetrimides, G) a S-layer protein, H) Methyl-glucamine; subject to the following provisos a) when the adjuvant chemical is administration to a mucosal surface, and selected from A, the composition is for b) when the particles are polymeric microcapsules. Therefore, the proposed after final amendment raises new issues requiring further search and consideration and potentially raise issues of new matter.

Therefore applicant's arguments filed January 19, 2006 have been fully considered but they are not persuasive, since the arguments are drawn to the proposed claim amendments, which are not being entered and are therefore not being addressed in this action.

The objection of claim 12 and 33 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is maintained. The objection is maintained because claim 33 is drawn to the composition, however neither the mode of administration nor the surface coating further limit the composition. The administration and surface coating do not add more components to the composition, therefore the claim is still objected to.

The written description rejection of claims 1, 4, 6-10, 12-13, 29 and 33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record. The rejection was on the grounds that the claims are so broad that they encompass every type of vaccine and biologically active agent which effects all types of diseases, disorders and infections in any type of animal. It is the examiner's position that the generic statements drawn to the vaccine composition and biologically active agent do not provide ample written description for the compounds since the claims do not describe a singe structural feature associated with the biologically active agent. Therefore applicants assertion that the invention is drawn to a composition that when utilized with known vaccines of known effect and administered non-parenterally, would facilitate induction of comparable levels of systemic immunity to that elicited by conventional sub-cutaneous and intra-muscular injection is not persuasive since the instantly described vaccine compositions do not teach a composition utilized with known vaccines of known effects.

The new matter rejection of claims 1, 4, 6-10, 12-13, 29 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. Therefore, it is the examiner's position that applicants' must specifically point to page and line number support for a vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes, the particles comprising a biologically active agent that generates a protective immune response in an animal to which it is administered', in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being selected from the instantly recited group.

The rejection of claims 1, 4, 6-9,12-13, 29 and 33 under 35 U.S.C. 102(b) as being anticipated by Duncan et al., (WO 94/20070 published September 15, 1994) is maintained for reasons already of record. It is the examiner's position that Duncan et al., teach a broad class of polycations and that there is no reason why a skilled person in the art would alight on the particular form of polycation. Furthermore Duncan et al., teach compositions comprising an adjuvant chemical having adjuvant properties wherein the adjuvants include block copolymers and that the antigens are more immunogenic when they are incorporated into the polymeric microparticles. Therefore, Duncan et al., clearly and with particularity points to specific positively charged cationic block copolymers.

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Duncan et al., (WO 94/20070 published September 15, 1994) in view of Griffin et al., (1998) is maintained for reasons already of record. As previously discussed and admitted by applicant, Griffin et al., clearly teach the microencapsulation of vaccine compositions comprising the V antigen with poly-(L-lactide), therefore the prior art teach that it would have been prima facie obvious at the time of applicants' invention to have used the known vaccine composition as taught by Duncan et al., and modify it to include poly-(L-lactide) and adjuvant agents in a microparticle formulation as taught by Griffin et al., since one of ordinary skill in the art would have a reasonable expectation of success in having a vaccine composition with a muchoadhesive which is beneficial since it has a low cost, is highly biocompatible, biodegradable, has gel-forming properties and is useful in microspheres systems and can be combined with antigens and cationic pluronic adjuvants in particle formation to achieve enhanced mucosal absorption.